NRLS Development

Domain 5 Patient Safety

October 2014

Contents

The current context

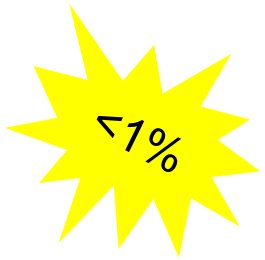
The National Reporting & Learning System (NRLS)

- The Health and Social Care Act 2012 makes NHS England responsible for "*systems for collecting and analysing information relating to the safety of services*" provided by the NHS
- The NRLS is a database of patient safety incident reports submitted by organisations across the NHS, and directly by patients, specifically for purposes of learning
- Trusts regularly upload incident reports from their local systems to the NRLS, where they are interrogated by national patient safety experts to spot trends, specific incidents of concern, or emerging risks to patient safety
- This triggers action to help address the identified issues/risks through the provision of advice and guidance, e.g. a Patient Safety Alert

NRLS Data

- NRLS has been in operation for around 10 years, and now contains ~10.25m reports

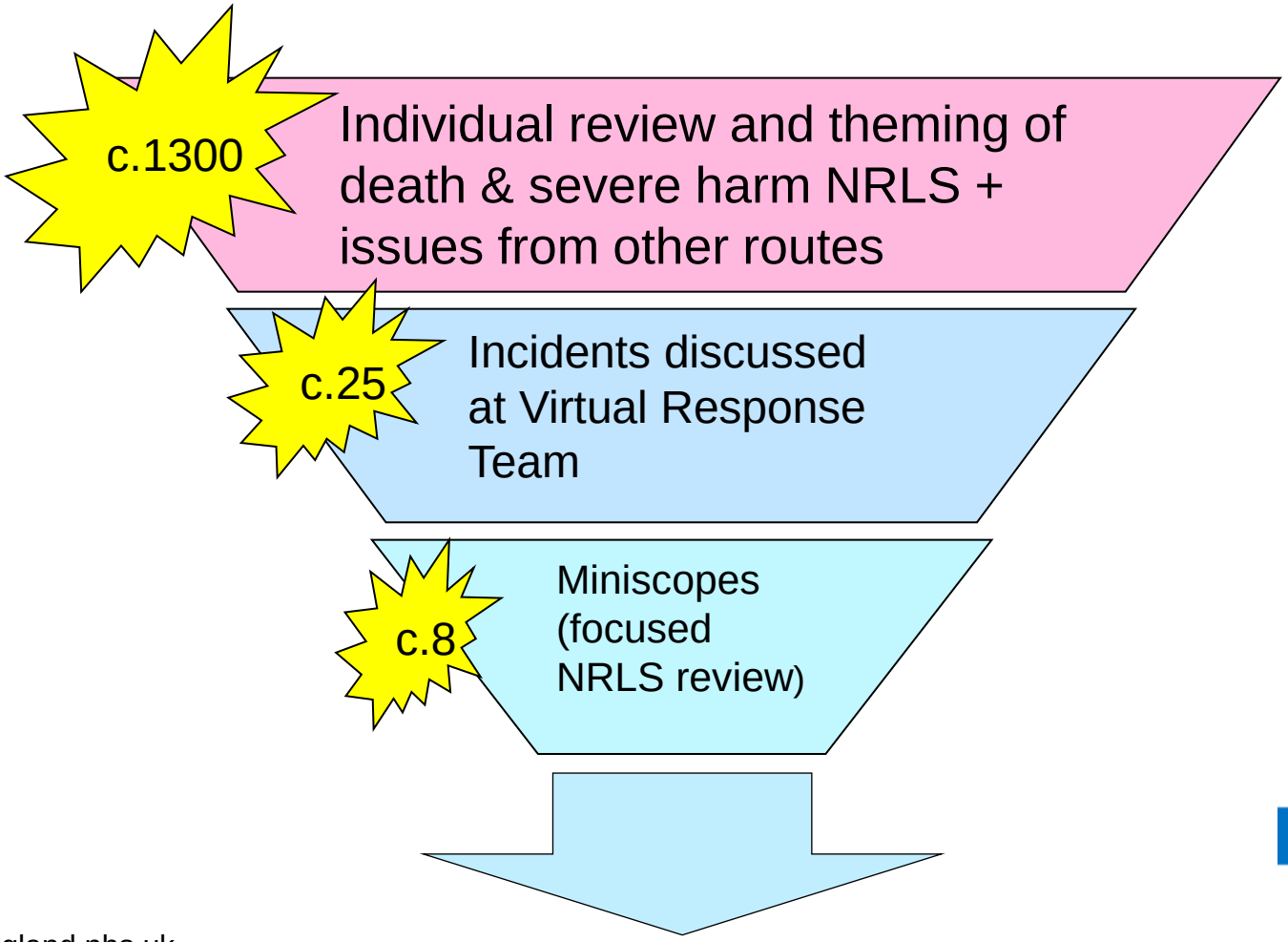
No Harm	6,975,235
Low	2,551,408
Moderate	624,191
Severe	67,471
Death	31,651
TOTAL	**10,249,956***



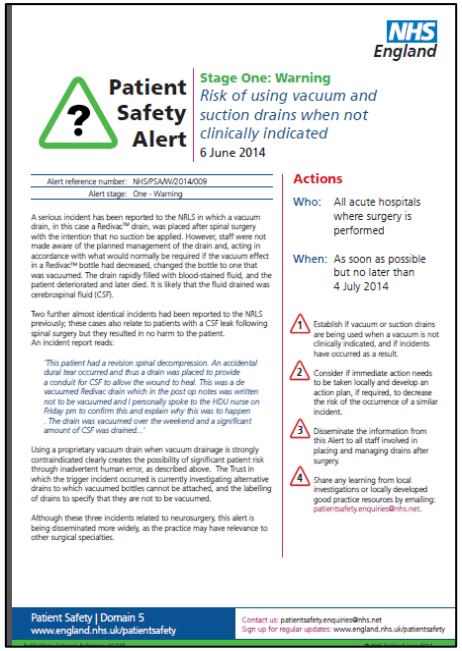
- Currently, only reports of severe harm or death are reviewed individually by national patient safety experts, due to capacity constraints
- Volume of reporting and requirements of the NRLS has increased – Indicator 5a, increasing local performance management

*Figures correct on 9th May 2014

Turning data into learning – in one month…



Patient Safety Alerts



Patient Safety Alert

Stage One: Warning

Risk of using vacuum and suction drains when not clinically indicated

6 June 2014

Alert reference number: NHS/PSA/W/2014/009

Alert stage: One - Warning

A serious incident has been reported to the NRLS in which a vacuum drain, in this case a Redivac™ drain, was placed after spinal surgery with the intention that no suction be applied. However, staff were not made aware of the planned management of the drain and, acting in accordance with what would normally be required if the vacuum effect in a Redivac™ bottle had decreased, changed the bottle to one that was vacuumed. The drain rapidly filled with blood-stained fluid, and the patient deteriorated and later died. It is likely that the fluid drained was cerebrospinal fluid (CSF).

Two further almost identical incidents had been reported to the NRLS previously; these cases also relate to patients with a CSF leak following spinal surgery but they resulted in no harm to the patient.
An incident report reads:

'This patient had a revision spinal decompression. An accidental dural tear occurred and thus a drain was placed to provide a conduit for CSF to allow the wound to heal. This was a de vacuumed Redivac drain which in the post op notes was written not to be vacuumed and I personally spoke to the HDU nurse on Friday pm to confirm this and explain why this was to happen . The drain was vacuumed over the weekend and a significant amount of CSF was drained...'

Using a proprietary vacuum drain when vacuum drainage is strongly contraindicated clearly creates the possibility of significant patient risk through inadvertent human error, as described above. The Trust in which the trigger incident occurred is currently investigating alternative drains to which vacuumed bottles cannot be attached, and the labelling of drains to specify that they are not to be vacuumed.

Although these three incidents related to neurosurgery, this alert is being disseminated more widely, as the practice may have relevance to other surgical specialties.

Actions

Who: All acute hospitals where surgery is performed

When: As soon as possible but no later than 4 July 2014

1. Establish if vacuum or suction drains are being used when a vacuum is not clinically indicated, and if incidents have occurred as a result.
2. Consider if immediate action needs to be taken locally and develop an action plan, if required, to decrease the risk of the occurrence of a similar incident.
3. Disseminate the information from this Alert to all staff involved in placing and managing drains after surgery.
4. Share any learning from local investigations or locally developed good practice resources by emailing: patientsafety.enquiries@nhs.net.

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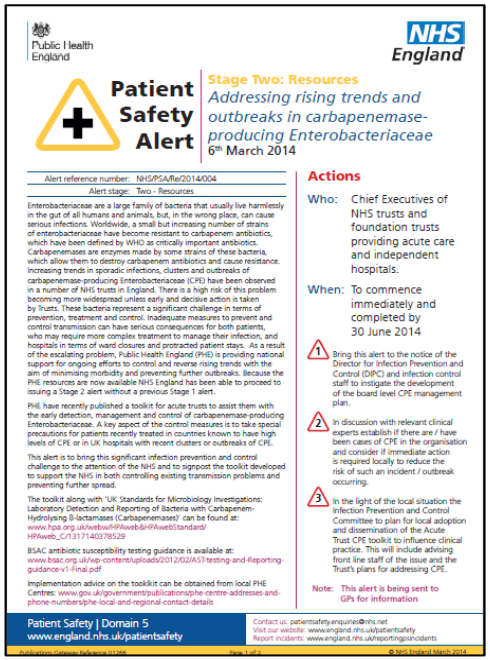

Public Health England

Patient Safety Alert

Stage Two: Resources

Addressing rising trends and outbreaks in carbapenemase-producing Enterobacteriaceae

6th March 2014

Alert reference number: NHS/PSA/Re/2014/004

Alert stage: Two - Resources

Enterobacteriaceae are a large family of bacteria that usually live harmlessly in the gut of all humans and animals, but, in the wrong place, can cause serious infections. Worldwide, a small but increasing number of strains of enterobacteriaceae have become resistant to carbapenem antibiotics, which have been defined by WHO as critically important antibiotics. Carbapenemases are enzymes made by some strains of these bacteria, which allow them to destroy carbapenem antibiotics and cause resistance. Increasing trends in sporadic infections, clusters and outbreaks of carbapenemase-producing Enterobacteriaceae (CPE) have been observed in a number of NHS trusts in England. There is a high risk of this problem becoming more widespread unless early and decisive action is taken by Trusts. These bacteria represent a significant challenge in terms of prevention, treatment and control. Inadequate measures to prevent and control transmission can have serious consequences for both patients, who may require more complex treatment to manage their infection, and hospitals in terms of ward closures and protracted patient stays. As a result of the escalating problem, Public Health England (PHE) is providing national support for ongoing efforts to control and reverse rising trends with the aim of minimising morbidity and preventing further outbreaks. Because the PHE resources are now available NHS England has been able to proceed to issuing a Stage 2 alert without a previous Stage 1 alert.

PHE have recently published a toolkit for acute trusts to assist them with the early detection, management and control of carbapenemase-producing Enterobacteriaceae. A key aspect of the control measures is to take special precautions for patients recently treated in countries known to have high levels of CPE or in UK hospitals with recent clusters or outbreaks of CPE.

This alert is to bring this significant infection prevention and control challenge to the attention of the NHS and to signpost the toolkit developed to support the NHS in both controlling existing transmission problems and preventing further spread.

The toolkit along with 'UK Standards for Microbiology Investigations: Laboratory Detection and Reporting of Bacteria with Carbapenem-Hydrolysing ß-lactamases (Carbapenemases)' can be found at: www.hpa.org.uk/webw/HPAweb&HPAweb/standard/HPAweb_C/1317140378529

BSAC antibiotic susceptibility testing guidance is available at: www.bsac.org.uk/wp-content/uploads/2012/02/AST-testing-and-Reporting-guidance-v1-Final.pdf

Implementation advice on the toolkit can be obtained from local PHE Centres: www.gov.uk/government/publications/phe-centre-addresses-and-phone-numbers/phe-local-and-regional-contact-details

Actions

Who: Chief Executives of NHS trusts and foundation trusts providing acute care and independent hospitals.

When: To commence immediately and completed by 30 June 2014

1. Bring this alert to the notice of the Director for Infection Prevention and Control (DIPC) and infection control staff to instigate the development of the board level CPE management plan.
2. In discussion with relevant clinical experts establish if there are / have been cases of CPE in the organisation and consider if immediate action is required locally to reduce the risk of such an incident / outbreak occurring.
3. In the light of the local situation the Infection Prevention and Control Committee to plan for local adoption and dissemination of the Acute Trust CPE toolkit to influence clinical practice. This will include advising front line staff of the issue and the Trust's plans for addressing CPE.

Note: This alert is being sent to GPs for information

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Visit our website: www.england.nhs.uk/patientsafety
Report incidents: www.england.nhs.uk/reportingpsincidents

MHRA

Patient Safety Alert

Stage Three: Directive

Improving medical device incident reporting and learning

20 March 2014

Alert reference number: NHS/PSA/D/2014/006

Alert stage: Three - Directive

NHS England and the MHRA are working together to simplify and increase reporting, improve data quality, maximise learning and guide practice to minimise harm from medical devices incidents by:

- sharing incident data between the MHRA and NHS England, reducing the need for duplicate data entry by frontline staff by developing a new integrated National
- giving new types of feedback from the NRLS
- clarifying medical device safety roles and ide and national level; and,
- setting up a National Medical Devices Safety

issues, identifying trends and actions to impr Patient Safety Improvement Collaboratives th

Continue to report separately to the MHRA a Another patient safety alert will then be issu

Actions (Target date for compl

All large* healthcare provider organisations including NHS trusts, community pharmacy multiples, home healthcare companies and those in the independent sector should:

1. identify a board level director (medical or nursing supported by a senior healthcare professional) or in community pharmacy, or home health care, a senior manager (for example a Superintendent Pharmacist) to have the responsibility to oversee medical device incident reporting and learning;
2. identify a Medical Devices Safety Officer (MDSO) and email their contact details to the Central Alerting System (CAS) team. This person will support local medical device incident reporting and learning, act as the main contact for NHS England and the MHRA and medical device manufacturers and be a member of the new National Medical Devices Safety Network; and,

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MHRA

Patient Safety Alert

Stage Three: Directive

Improving medication error incident reporting and learning

20 March 2014

Alert reference number: NHS/PSA/D/2014/005

Alert stage: Three - Directive

NHS England and MHRA are working together to simplify and increase reporting, improve data report quality, maximise learning and guide practice to minimise harm from medication errors by:

- sharing incident data between MHRA and NHS England reducing the need for duplicate data entry by frontline staff;
- providing new types of feedback from the National Reporting and Learning System (NRLS) and MHRA to improve learning at local level;
- clarifying medication safety roles and identifying key safety contacts to allow better communication between local and national levels; and,
- setting up a National Medication Safety Network as a new forum for discussing potential and recognised safety issues, identifying trends and actions to improve the safe use of medicines. The network will also work with new Patient Safety Improvement Collaboratives that will be set up during 2014.

The Yellow Card Scheme for reporting suspected adverse drug reactions to the MHRA will continue to operate as normal.

Actions (Target date for completion 19 September 2014)

All large* healthcare providers including NHS Trusts, community pharmacy multiples, home healthcare companies and those in the independent sector should:

1. identify a board level director (medical or nursing supported by the chief pharmacist) or in community pharmacy and home health care, the superintendent pharmacist, to have the responsibility to oversee medication error incident reporting and learning;
2. identify a Medication Safety Officer (MSO) and email their contact details to the Central Alerting System (CAS) team. This person will be a member of a new National Medication Safety Network, support local medication error reporting and learning and act as the main contact for NHS England and MHRA; and,
3. identify an existing or new multi-professional group to regularly review medication error incident reports, improve reporting and learning and take local action to improve medication safety.

Small* healthcare providers including general practices, dental practices, community pharmacies and those in the independent sector should:

4. continue to report medication error incidents to the NRLS using the e-form on the NRLS website, or other methods and take action to improve reporting and medication safety locally, supported by medication safety champions in local professional committees, networks, multi-professional groups and commissioners.

Healthcare commissioners including Area Teams, and Clinical Commissioning Groups are invited to:

5. identify a MSO and email their contact details to the CAS team. This person will be a member of the National Medication Safety network, support reporting and learning and take local actions to improve medication safety. The MSO can also use learning to influence policy, planning and commissioning as part of clinical governance in the commissioning organisation; and,
6. regularly review information from the NRLS and the MHRA to support improvements in reporting and learning and to take local action to improve medication safety. This should done by working with medication safety champions in local professional committees and networks, and with a new or existing multi-professional group.

Supporting information

*More detailed information to support the implementation of this guidance is available at: www.england.nhs.uk/patientsafety/PSA

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Contact NHS England: patientsafety.enquiries@nhs.net
Contact MHRA: pharmacovigilanceservice@mhra.gsi.gov.uk

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http://www.england.nhs.uk/ourwork/patientsafety/psa/

The future of reporting and learning

The task

- We need a reporting and learning system that will help improve the ability:
  - of **all healthcare-associated organisations** to report more effectively (eg non-acute settings, Independent Sector, devolved nations)
  - to develop **better learning** that supports more improvement
  - to provide **greater transparency** of patient safety data
  - to **reduce risks** associated with:
    - **Duplication and omission**
    - lack of **standardisation**
    - the gap between the capabilities of the NRLS and the **needs of the NHS, patients, and other users**
- Therefore, seeking to develop a successor to the NRLS, building on its success and making it fit for the future

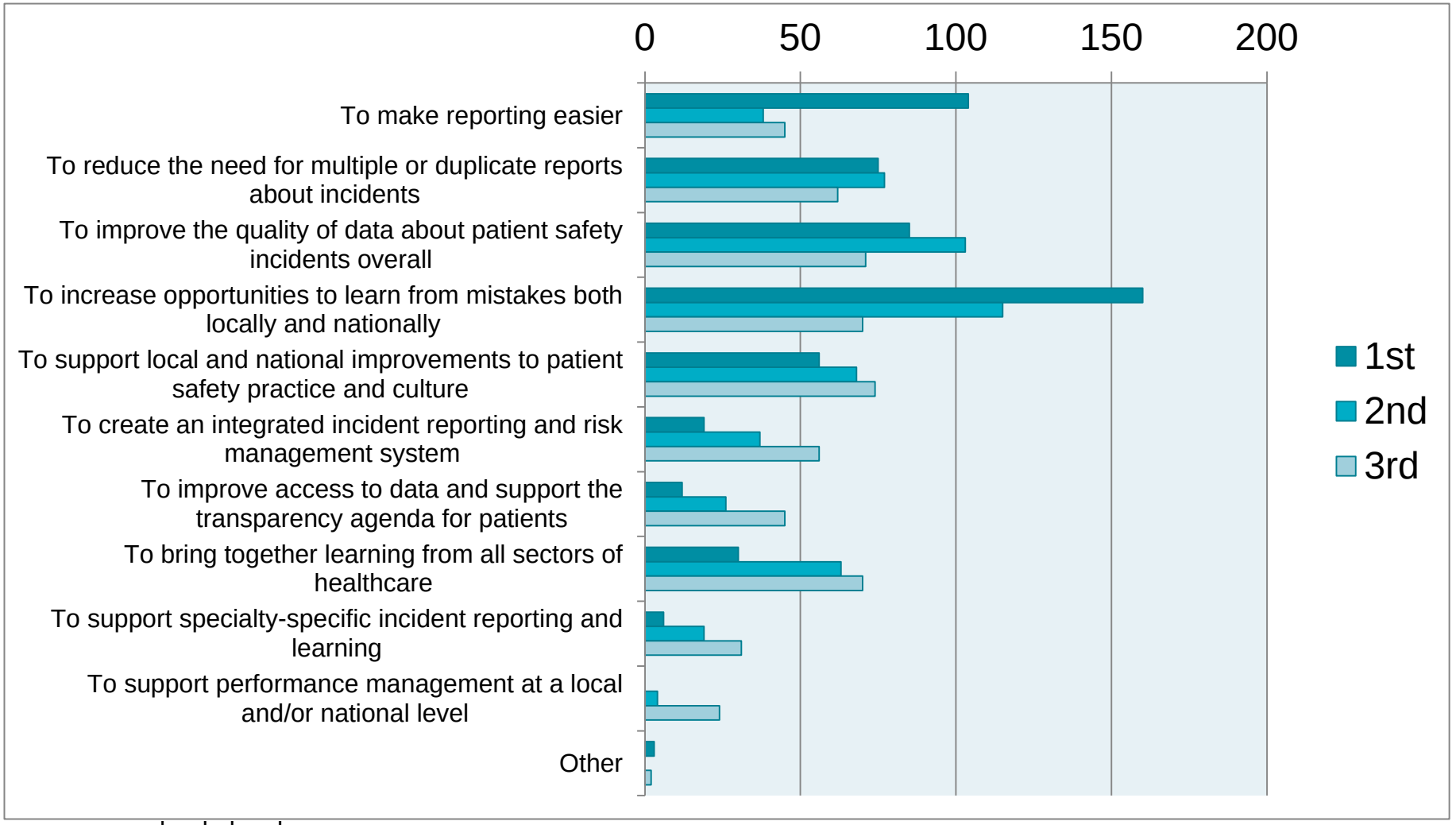
Confounding factors

- Many people, with differing needs, have an interest in the data:
  - Ministers
  - Patients/Carers/the public
  - Other bodies – CQC, MHRA, commissioning groups
  - Professional organisations
  - Provider organisations
  - Individuals – NHS staff, researchers, policy officials
- Other parallel systems doing similar tasks: STEIS (for Serious Incidents – not just in patient safety), specialities (eg CORESS for surgery), Devolved Governments – Wales, Scotland and Northern Ireland…

NRLS Questionnaire

- In May 2014, stakeholders were asked to complete a short questionnaire about their views on the future of reporting and learning systems for patient safety incident data
- Over 600 people responded
- High level results can be viewed here: https://fs2.formsite.com/res/resultsReportCharts?EParam=m%2FOmK8apOTAd8Y4p2frd7OmbtmIuQSUj2CO%2BcxzjberWeVIiB0%2FmIAAl6fwFDdon2%2BycBO9iaxE%3D
- Respondents identified their key aims for a new system

Summary: “If a single patient safety incident reporting and learning system were introduced, what do you think its first, second and third priority aims should be?”



Challenges identified

Key challenges – the patient perspective

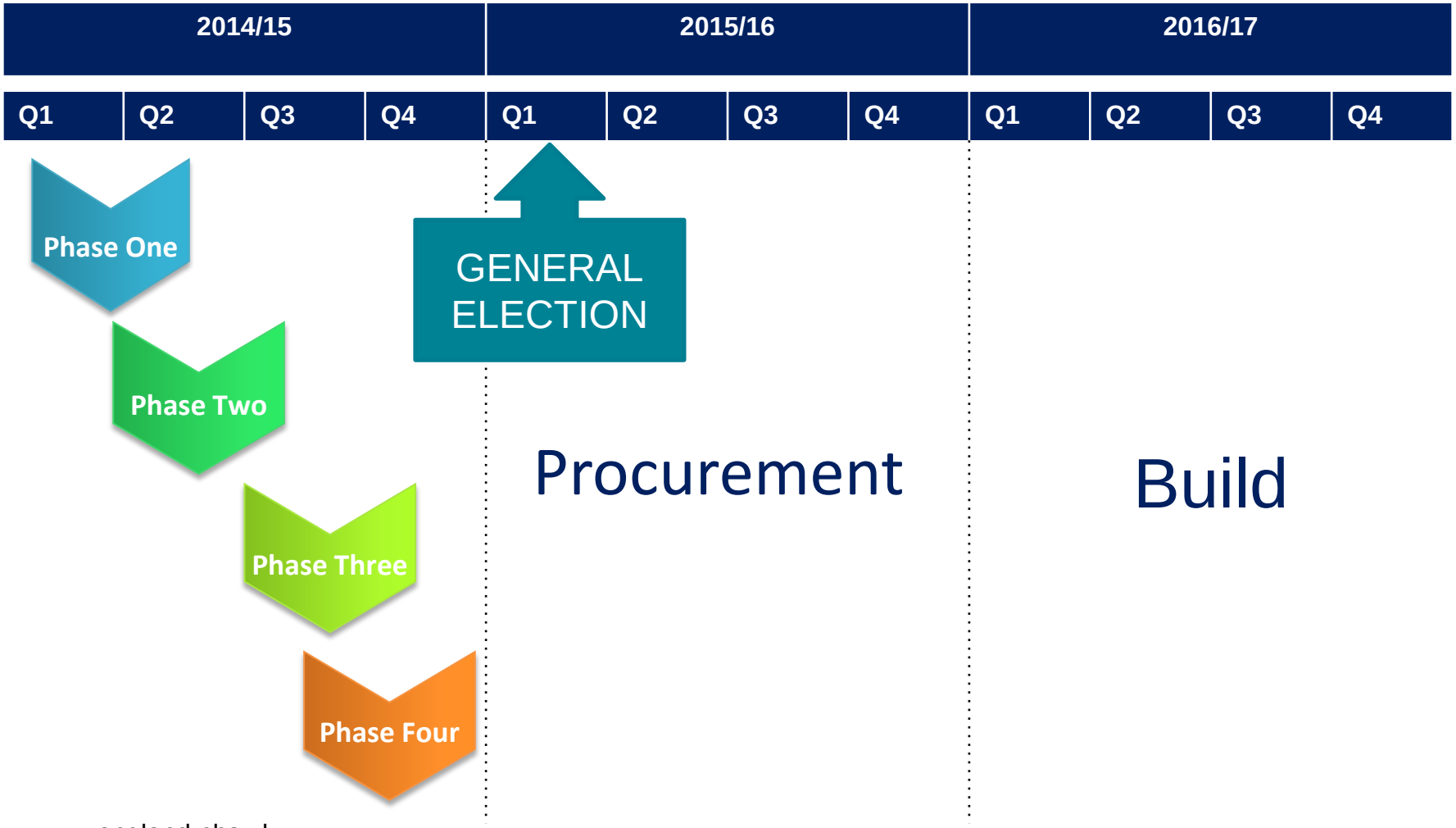
- A **“one experience” system** linking all feedback in all settings - complaints, learning, compliments - that is **easy to access** and simple to use
- Allow for measurable **and** narrative feedback – remember **patient experience makes up 1/3 of quality**
- Clarity over the **ownership** of a report, learning, and actions
- **Cultural shift within the patient community** as well as NHS towards ownership of health, experiences, and learning opportunities
- See evidence of **commissioners** taking an active role in learning, improvement and the reduction of harm
- Provide appropriate **support and information** to patients wishing to report or contribute to learning - eg PALS, leaflets, follow-up

Key challenges so far…

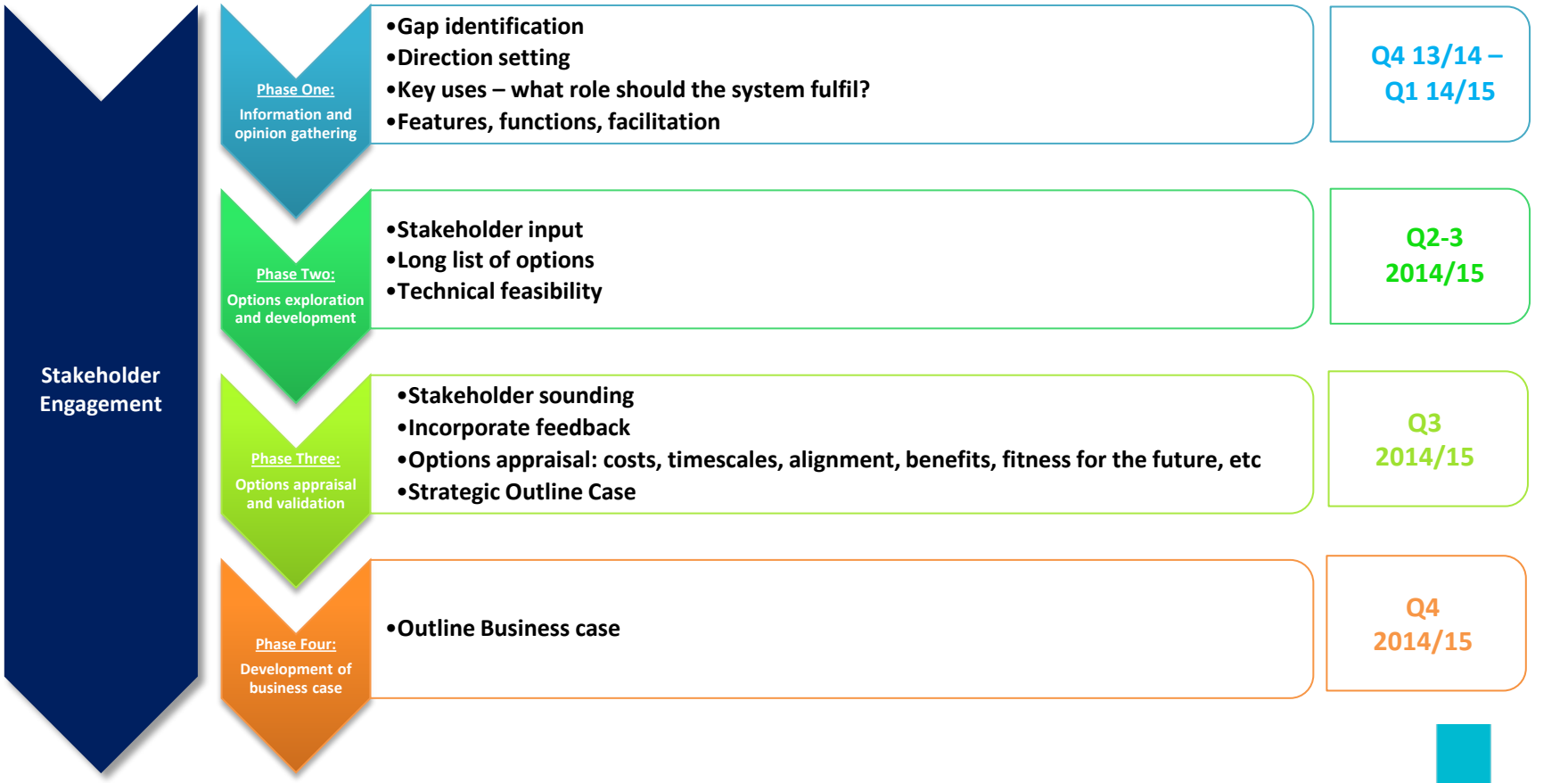
- Keep **learning** as a priority
- Expand and tailor **feedback**
- **“Joined-up” data** – integration and interoperability
- Supports **prevention** rather than cure – near miss data?
- **Simplicity** – one port of call, accessible, intuitive
- Supports and enables **cultural change**; local AND national
- **Multi-use**: standardised data, accessible, flexible, future-proof
- Fits current **NHS delivery models**

Timelines

High level timeline



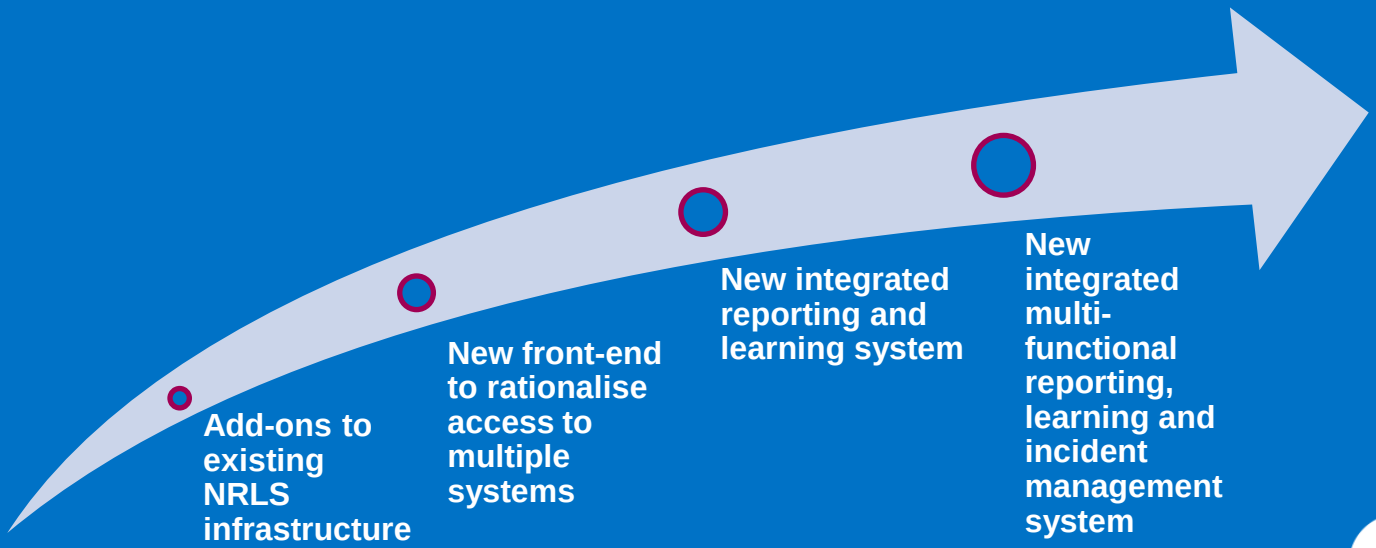
Timeline for 2014/15



Possible solutions

Options identification

- Turning the intelligence gathered from stakeholders into options to develop and appraise
- Working with technical, legal, economic and industry colleagues to draw up outline plans for each option



To be assessed against a five-case model for progression

Some desirable features 1

- Single system for all patient safety incident reports – mandatory or for learning
- Accessible from multiple settings, across providers, remotely, and to patients/the public
- Specific patient/public-facing access points, linked to existing feedback routes and channels of support
- Some incident management functionality to cover the software gap in non-acute settings
- Remodelling of data capture to better align with current conceptualisations of risk and harm
- Governed by appropriate data standards to improve data quality and utility

Some desirable features 2

- Interoperable with other data sources such as patient records and other local systems, both push and pull
- Linked to complaints systems, to incorporate learning from other sources of patient input
- Open up database to more generalised access – increase opportunities for review, scrutiny and research, including by patients/the public
- Built-in tools to enable meaningful analysis for all users
- Free-text analysis tools to help process large quantities of narrative data

Some desirable features 3

- Expand types and routes of feedback – tailored to user groups, reinforcing value of reporting
- Surveillance function – automatically (or otherwise) detects trends that may be cause for concern
- Supports and enables patient safety culture at ground level
- …and a wide variety of other possibilities!